

09/046,840 03/24/98


UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

ENZ-56 (DIV3)

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NUMBER	FILING DATE	HM12/03/98	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
RONALD C FEDUS CORP & PATENT COUNSEL		GUZO, D		
ENZO THERAPEUTICS INC				
ENZO BIOCHEM INC				
527 MADISON AVE 9TH FLOOR				
NEW YORK NY 10022				

1626
EXAMINER

03/18/99

ART UNIT	PAPER NUMBER
----------	--------------

7

DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☒ Responsive to communication(s) filed on 12/18/98
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire Three (3) month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 68-84 is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 68-84 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claims _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449. Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

- SEE OFFICE ACTION ON THE FOLLOWING PAGES -

Art Unit: 1636

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

2. Claims 68-79 and 81-84 are rejected under 35 U.S.C. 102(e) as being anticipated by Wong-Staal et al.

This rejection is maintained for reasons of record in the previous Office Action (Paper #4) and for reasons outlined below.

Applicants traverse this rejection by asserting that the Wong-Staal et al. reference does not disclose nucleic acid constructs wherein the second viral nucleic acid or the second nucleic acid construct is structurally different from the first (I) viral nucleic acid or the first (ii) nucleic acid construct, or more than one packaging component for the second viral vector is different from said first viral vector packaging component or components (b), or both.

Applicants' arguments filed 12/18/98 have been considered but are not deemed persuasive. As noted in the previous Office Action, Wong-Staal et al. recites the generation of a recombinant vector (a first vector) comprising sequences from retrovirus and AAV genomes, wherein said first vector can produce a second vector which can be single or double stranded RNA or DNA and

Art Unit: 1636

hence is structurally different from the first vector. With regard to the differences in packaging components, it is noted that packaging components comprising different surface or envelope components provided in the packaging cell can package the AAV portion of a chimeric AAV/HIV vector into AAV particles which have more than one packaging component different from the original HIV particle. Therefore, it must be assumed that Wong-Staal et al. teaches the invention as claimed.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 68 and 70-74 are rejected under 35 U.S.C. 102(b) as being anticipated by Salmons et al.

Applicants' traverse of this rejection is similar to the traverse of the above 35 USC 102(e) rejection of claims 68-79 and 81-84.

Salmons et al. teaches the claimed invention because the reference teaches a first and second vector wherein the two vectors differ in chemical structure (i.e. a DNA provirus vector vs. an RNA viral vector) wherein the second vector is capable of expressing an exogenous gene in a

Art Unit: 1636

target cells and said vector contains a promoter, enhancer, termination sequences, etc. Therefore, Salmons et al. anticipates the claimed invention.

Applicants request that the Sequence Listing from the parent application be used to prepare a file for the instant application is acknowledged and is acceptable. A Sequence Listing for the instant application will be prepared.

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

2. Claim 80 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wong-Staal et al.

Art Unit: 1636

in view of Bank et al.

Applicants claim a packaging cell line (such as NIH 3T3) for propagating the vector of claim 68, wherein the first vector comprises a retrovirus and wherein the second vector comprises an adeno-associated virus.

Wong-Staal et al. is applied as in the above 35 USC 102(e) rejection of claims 68-79 and 81-84. Wong-Staal et al. does not recite the claimed packaging cell lines.

Bank et al. recites the use of the NIH 3T3 cell line as a packaging cell line for retroviral vectors.

The claimed subject matter is disclosed by Wong-Staal et al. with the exception of using the recited packaging cell lines recited in claim 80. The ordinary skilled artisan would have been motivated to use a well known packaging cell line (such as NIH 3T3) to package the claimed vectors since Bank et al.; teaches use of the NIH 3T3 cell line for packaging retroviral vectors. It would have been obvious for the ordinary skilled artisan to use a cell line such as NIH 3T3 because Bank et al. indicates that this cell line can be used to package retroviral vectors. Indeed, applicants themselves admit that the packaging cell line for the claimed vectors can be selected from a variety of packaging cell lines which are known in the art (See Specification, p. 28). Given the well known teachings of the cited references and the level of skill in the art at the time the invention was made, it must be considered that the ordinary skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

Art Unit: 1636

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 78 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The rejection of claim 78 is maintained for reasons of record in the previous Office Action and for reasons outlined below.

Applicants traverse this rejection the term “native” is sufficiently clear when read in light of the specification.

Applicants’ arguments have been considered but are not persuasive. While applicants’ explanation of the meaning of the term “native” with relation to the cell line for the viral vector is agreed with, it is again noted that the claimed viral vectors can comprise portions of two or more viruses, each with it’s own “native” cell line. Therefore, it is unclear what “native” cell is being referred to in the claim.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner

Art Unit: 1636

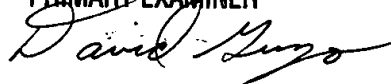
should be directed to David Guzo whose telephone number is (703) 308-1906. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, George Elliott, can be reached on (703) 308-4003. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David Guzo
March 15, 1999

DAVID GUZO
PRIMARY EXAMINER

A handwritten signature in cursive script, appearing to read "David Guzo", written over the printed name and title.